REMARKS

Claims 1-59 will be pending upon entry of this Letter Amendment B. Claims 1 and 18 have been amended to correct typographical errors. Claims 31-59 have been withdrawn as directed to a non-elected invention. Applicants reserve the right to file divisional applications directed to the non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claim 24 under 35 U.S.C. §112, first paragraph

Reconsideration is requested of the rejection of claim 24 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Office has stated that the specification does not teach how to use glucosylceramide (citing no amounts, weights or percentages given, and no discussion as to how it is incorporated into the tissue product).

MPEP 2163 states that "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Furthermore, with regard to originally filed claims, it is well accepted that "a satisfactory

description may be [solely] in the claims or any other portion of the originally filed specification."[1]

Applicants note that glucosylceramide is set forth in claim 24 as originally filed. Specifically, original claim 24 reads: "The tissue product as set forth in claim 23 wherein the ceramide is glucosylceramide." Written description support for glucosylceramide may therefore be found in original claim 24.

With regard to the Office's comments regarding amounts, weights, percentages, and method for incorporating glucosylceramide into the tissue product, Applicants respectfully note that in order to satisfy written description, the claimed invention must be described in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Furthermore, subject matter that is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. Specifically, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate

[1] MPEP §2163. *See also id.*, citing In re Koller, 613 F.2d 819 (CCPA 1980) (original claims constitute their own description); MPEP 2163.06 ("The claims as filed in the original specification are part of the disclosure."); MPEP §608.01(l) ("In establishing a disclosure, applicant may rely not only on the description and drawings as filed but also on the original claims if their content justifies it. Where subject matter not shown in the drawings or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim.").

description requirement is met.[2] Applicants assert that one skilled in the art of skin care and skin care compositions would know the amounts, weights, percentages, and method for incorporating glucosylceramide into a tissue product. Specifically, Bowser (U.S. 5,342,976), cited by the Office in the present Office action as prior art, teaches topical compositions including (a) a long chain ω-hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b) for moisturizing and treating skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, in Example 3, Bowser teaches the use of ω-(O-linoleoyl) glucosylceramide in its composition for moisturizing and treating skin. Furthermore, Bowser teaches that its composition can be incorporated into a tissue product such as a tissue wipe and then used to treat the skin.[3] With such a teaching in the prior art, one skilled in the art would know amounts and methods of using ceramides such as glucosylceramides for moisturizing and lubricating skin such as required in Applicants' instant claim 24.

Furthermore, Applicants provide adequate description for one skilled in the art to conclude that Applicants had possession of the invention of using glucosylceramide in a tissue product. Specifically, as disclosed in originally filed claim 24, glucosylceramide can be included in the moisturizing

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[2] *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); Vas-Cath, 935 F.2d 1555, 1563 (Fed. Cir. 1991); Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).
[3] U.S. 5,342,976 at column 16, lines 39-44.

and lubricating composition. The composition is then incorporated onto at least one surface of the tissue product. As described in Applicants' instant specification at paragraphs 17-25, a tissue product can be produced by first depositing a papermaking furnish on a foraminous forming wire (i.e., web) and then dewatering the web by pressing the web and drying at an elevated temperature.[4] As described more fully in paragraph 28 of the instant specification, once the tissue product is made, the moisturizing and lubricating composition, which can optionally include ceramides such as glucosylceramide, is applied to one or both surfaces of the tissue product. Furthermore, as described in paragraph 67, the compositions are applied to one or both surfaces of the tissue product in an amount of from about 0.05 g/m^2 to about 100 g/m^2, more preferably from about 1.0 g/m^2 to about 40 g/m^2, and even more preferably from a bout 4 g/m^2 to about 15 g/m^2.

Based on the foregoing, possession is clearly shown by the disclosure of glucosylceramide in original claim 24. Furthermore, the amount and method of incorporating glucosylceramide into a tissue product is well known in the art. As such, Applicant's disclosure of glucosylceramide in the moisturizing and lubricating composition is sufficient to meet the written description requirement and, as such, this rejection should be withdrawn.

[4] *See Id.* Specification at paragraph 17.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-14 and 25-30 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682).

Claim 1 is directed to a tissue product comprising a tissue paper and a moisturizing and lubrication composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Klofta, et al. disclose an anhydrous lotion composition for killing viruses and bacteria in addition to imparting a soft, lubricious, lotion-like feel when applied to tissue paper. The lotion composition comprises at least one antimicrobial selected from an antiviral, antibacterial, and mixtures thereof; at least one hydrophilic solvent; at least one skin conditioning agent; and at least one hydrophilic surfactant. When used in the lotion formulation, the antiviral is present in the lotion composition in an amount of from about 1% (by weight) to about 60% (by weight) and the antibacterial is present in an amount of

from about 0.1% (by weight) to about 6% (by weight). Hydrophilic solvents can include glycol type solvents such as polyethylene glycols, glycerin, ethylene glycol, propylene glycol, polypropylene glycol, ethanol, isopropanol, hexylene glycol, and mixtures thereof and are present in the lotion composition in an amount of from about 5% (by weight) to about 60% (by weight).[5] Hydrophilic surfactants such as ethoxylated alcohols are present in the lotion formulation in an amount of from about 0.1% (by weight) to about 60% (by weight). Skin conditioning agents include petroleum-based agents such as mineral oil and petrolatum; fatty acid ester type agents, fatty alcohol type agents, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures thereof and are present in the lotion composition in an amount of from about 0.1% (by weight) to about 60% (by weight).[6] Typically, the skin conditioning agents have either a plastic or fluid consistency at 20°C (i.e., ambient temperatures).[7] As the skin conditioning agents have a plastic or fluid consistency at 20°C, they tend to flow or migrate on the surface of the tissue product. The lotion composition can further optionally include an immobilizing agent such as C_{12}-C_{22} fatty alcohols and C_{12}-C_{22} fatty acids in amounts of from about 5% (by weight lotion formulation) to about 60% (by weight lotion formulation).[8]

Significantly, Klofta, et al. fail to disclose a moisturizing and lubricating composition wherein no more than

[5] U.S. 6,238,682 at column 17, lines 41-42.
[6] *Id.* at column 19, lines 23-26.
[7] *Id.* at column 17, lines 50-52.
[8] *Id.* at column 22, lines 51-55.

about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Furthermore, as noted by the Office, Klofta, et al. fail to teach the components of an emollient, humectant, immobilizing agent, and compatibilizing agent in the amounts required in claim 1.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some combinations would have been obvious where others would not.[9] The Office has clearly failed to meet its burden under number (1) and/or (2) above, as the cited reference does not teach or suggest all of the claimed limitations and there is no apparent reason to modify the reference to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to

one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as noted above, Klofta, et al. fail to teach or suggest a moisturizing and lubricating composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. These are significant aspects of Applicants' invention.

As noted in the specification of the present application, liquid components of the moisturizing and lubricating compositions are important in that they provide plasticity and help avoid products that are too hard, brittle, or flaky. However, compositions that contain a high proportion of components that are liquid at room temperature are more difficult to process. Furthermore, if the composition contains too high a proportion of liquid components, the liquid components of the composition may migrate away from the surface of the substrate to which the composition is applied, and into the matrix of the fabric of the substrate. It is thus important that the compositions comprise a certain percentage of components that are solid at room temperature. In particular, the solid components, such as the immobilizing agents, provide a network that is capable of supporting the liquid components

[9] Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) *See also* KSR Int'l Co. v. Teleflex, Inc., et al. 550 US____, 2007

within it and, therefore, preventing their migration through the substrate. If the solid portion of the composition is too small, the network may be overwhelmed by the large liquid portion, and the solids portion may be unable to support the liquids in the network. *See* Specification at ¶55. To address this problem, the compositions of the present invention comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature.

There is simply nothing in Klofta, et al. stating that the compositions disclosed therein should comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature. Nor is there any reason for one skilled in the art, reading Klofta, et al., to modify the compositions described therein to arrive at a moisturizing and lubricating composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature.

As noted above, the lotion compositions of Klofta, et al. comprise from about 0.1% (by weight) to about 60% (by weight) skin conditioning agent. As will be apparent to those skilled in the art, and further disclosed in Klofta, et al., the skin condition agents have a fluid consistency (i.e., liquid) at room temperature. Thus, the lotion compositions set forth in Klofta, et al. have higher percentages of components that are liquid at

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WL 1237837 at 12 (2007).

room temperature than the compositions set forth in Applicants' claim 1. Based on this disclosure, there is no apparent reason for one skilled in the art to avoid preparing the lotion compositions of Klofta, et al. having more than 50% by weight of components that are liquid at room temperature, in direct opposition to the compositions set forth in Applicants' claim 1.

Along these lines, Applicants note that Klofta, et al. also fail to teach or suggest the desired ranges of emollient, humectant, immobilizing, and compatibilizing agent in their lotion composition. The Office states that although Klofta, et al. fail to teach all the percentages recited in instant claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results. Applicants respectfully disagree that the desired amounts are a result of routine experimentation.

As noted above, the compositions of the present disclosure comprise a certain percentage of components, such as 30% (by weight) to about 90% (by weight) immobilizing agents to ensure that at least 50% (by weight) of the components are solid at room temperature. Immobilizing agents, as noted above, are essential in providing a network that is capable of supporting the liquid components within it and, therefore, preventing their migration through the substrate. Significantly, the Klofta, et al. reference discloses that the immobilizing agent is merely an **optional** ingredient in their lotion compositions. Furthermore, when the immobilizing agents are present, Klofta, et al.

disclose using significantly lower amounts of immobilizing agent. These lower amounts of immobilizing agent in Klofta, et al., particularly in combination with the higher amounts of humectant- and emollient-like skin conditioning agents, will not provide compositions having the necessary consistency to prevent migration of the composition into the substrates of the tissue product.

As Klofta, et al. fail to disclose compositions comprising no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature and including the amounts of components as required in claim 1, and further, there is no apparent reason for one skilled in the art to modify the compositions of Klofta, et al. to arrive at the compositions of claim 1, claim 1 is patentable over the Klofta, et al. reference.

Claims 2-14 and 25-30 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 15-22 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437).

Claim 1 is discussed above.

Klofta, et al. is discussed above. Significantly, as discussed above, Klofta, et al. fail to disclose compositions comprising no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature and including the amounts of components as required in claim 1. Krzysik, et al. fail to overcome the above shortcomings. Specifically, Krzysik, et al. disclose a skin health enhancing soft wet wipe comprising an oil-in-water emulsion composition. The oil-in-water composition comprises a natural fat or oil, sterol or sterol derivative, humectant, emulsifying surfactant, and water. Specifically, in one exemplary embodiment, the oil-in-water composition comprises from about 0.1 to about 30 weight percent of natural fats or oils, from about 0.1 to about 10 weight percent of a sterol or sterol derivative, from about 0.1 to about 99.5 weight percent of an humectant, and from about 0.5 to about 20 weight percent of an emulsifying surfactant having an HLB range of about 7 to about 18, from about 45 to about 99.5 weight percent of water and the pH of the emulsion adjusted to a pH of about 4 to about 7.[10]

Significantly, no where in Krzysik, et al. is it taught or suggested that the oil-in-water composition can comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature. Specifically, as noted above, the compositions of Krzysik, et al. comprise from about 45% (by weight) to about 99.5% (by weight) water. Furthermore,

[10] U.S. 6,440,437 at column 3, lines 21-29.

the specific examples of the compositions set forth in the Examples of Krzysik, et al. all comprise more than 88wt.% water.[11] As will be apparent to those skilled in the art, water is liquid at room temperature. Thus, the preferred embodiments, and all of the specific examples of compositions set forth in Krzysik, et al. have significantly higher percentages of components that are liquid at room temperature than that of the compositions set forth in Applicants' claim 1. Based on this disclosure, one skilled in the art would in fact be motivated by Krzysik, et al. to prepare compositions that comprise more than 50% (by weight) by weight of components that are liquid at room temperature, in direct opposition to the compositions set forth in Applicants' claim 1.

Furthermore, even if Krzysik, et al. did disclose each and every element (which, as noted above, Applicants assert that Krzysik, et al. do not) there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al. and Krzysik, et al. references to arrive at Applicants' claim 1. Specifically, a close reading of the Krzysik, et al. reference actually teaches away from the combination of the Klofta, et al. and Krzysik, et al. references.

Specifically, as disclosed in Klofta, et al., it is desirable for the lotion compositions to be anhydrous lotions, typically comprising less than about 5% (by weight) water,

[11] *Id.* at column 17, line 22 through column 18, line 21. Specifically, the formulas for the Examples comprise water in the amounts of: Formula 1 (90.4wt.%); Formula 2 (88wt.%); Formula 3 (89.6wt.%); Formula 4 (88.6wt.%); Formula 5 (95wt.%); Formula 6 (92wt.%); and Formula 7 (92.47wt.%).

preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.[12] As noted above, however, the Krzysik, et al. composition comprises from about 45% to about 99.5% by weight water. The water contained in the Krzysik, et al. composition may be a mixture of water and alcohol. The amount of alcohol in the water is up to about 70 weight percent of the water and alcohol solution.[13] Even if alcohol is present in 70 weight percent of the water and alcohol solution, however, the compositions of Krzysik, et al. comprise at least about 13.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Krzysik, et al. reference, which are desirably incorporated into compositions having at least 13.5% by weight water with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

Claims 15-22 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

4. <u>Rejection of the Claims under 35 U.S.C. §103(a)</u>

Reconsideration is requested of the rejection of claims 1 and 23-24 under 35 U.S.C. §103(a) as being unpatentable over

[12] U.S. 6,238,682 at column 10, lines 51-57.
[13] U.S. 6,440,437 at column 3, lines 61-67.

Klofta, et al. (U.S. Patent No. 6,238,682) in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 is discussed above.

Klofta, et al. is discussed above. Significantly, as discussed above, Klofta, et al. fail to disclose compositions comprising no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature and including the amounts of components as required in claim 1. Bowser, et al. fail to overcome the above shortcomings. Specifically, Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω-hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

Significantly, no where in Bowser, et al. is it taught or suggested that the composition can comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components

that are solid at room temperature. Specifically, as noted above, the compositions of Bowser, et al. comprise water as the carrier vehicle for the active ingredient of the composition. As disclosed in column 16, lines 3-5, the composition typically comprises from 15% to 99.9999% by weight, and preferably 50% to 99.5% by weight of the vehicle (i.e., the composition comprises from 15% to 99.9999% by weight water). Furthermore, the specific examples of the compositions set forth in Examples 1-7 and 9-19 of Bowser, et al. all comprise 50wt.% or greater water.[14] As will be apparent to those skilled in the art, water is liquid at room temperature. Thus, the preferred embodiments, and most of the working examples of compositions set forth in Bowser, et al. have significantly higher percentages of components that are liquid at room temperature than that of the compositions set forth in Applicants' claim 1. Based on this disclosure, one skilled in the art would in fact be motivated by Bowser, et al. to prepare compositions that comprise more than 50% by weight of components that are liquid at room temperature, in direct opposition to the compositions set forth in Applicants' claim 1.

Furthermore, even if Bowser, et al. did disclose each and every element (which, as noted above, Applicants assert that Bowser, et al. do not) there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al. and Bowser, et al. references

[14] U.S. 5,342,976. Specifically, the formulas for the Examples comprise water in the amounts of: Examples 1-3 (89.89 wt.%); Examples 4-7 (83.44 wt.%); Example 9 (72.8 wt.%); Example 10 (73.8 wt.%); Example 11 (89.42 wt.%);

to arrive at Applicants' claim 1. Specifically, a close reading of the Bowser, et al. reference actually teaches away for the combination of the Klofta, et al. and Bowser, et al. references.

Specifically, as noted above, it is desirable for the lotion compositions of Klofta, et al. to be anhydrous lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.[15] As noted above, however, the Bowser, et al. composition can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

Claims 23-24 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Example 12 (89.35 wt.%); Example 13 (84.3 wt.%); Example 14 (87.3 wt.%); Example 15 (54 wt.%); Example 16 (54 wt.%); and Examples 17-19 (>90 wt.%).

[15] U.S. 6,238,682 at column 10, lines 51-57.

5. Double Patenting Rejections

Claims 1-30 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,969 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-30 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 19-1345.

Respectfully Submitted,

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